VASCULAR AND ENDOVASCULAR TECHNIQUES

Thomas L. Forbes, MD, Section Editor

Initial experience with a new fenestrated stent graft

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Objectives: **The Anaconda fenestrated stent graft (Vascutek, Inchinnan, United Kingdom) is a new device that can easily be repositioned during deployment. This study evaluated its feasibility for treating abdominal aortic aneurysms with inadequate infrarenal sealing zones.**
Methods: **Patients undergoing stent graft placement at two institutions in the United Kingdom were recruited.**
Results: **A total of 12 visceral vessels were accommodated with 8 fenestrations for renal arteries and 4 superior mesenteric artery valleys/scallops in 4 patients. One type Ib endoleak was identified at the 1-month follow-up and successfully treated.**
Conclusions: **The Anaconda fenestrated stent graft device can be used for the repair of abdominal aortic aneurysms with hostile anatomy and has acceptable immediate and short-term results. (J Vasc Surg 2011;54:1832-8.)**

Endovascular aneurysm repair (EVAR) has a distinct perioperative mortality advantage compared with open repair for asymptomatic abdominal aortic aneurysms (AAA).[1] In addition, benefits over open repair of shorter hospital stay, reduced surgical morbidity, and earlier return to normal activities are reported.[2] The greatest limitation to EVAR use is unfavorable aneurysm anatomy. More specifically, a short (<15 mm) and angulated (>60°) proximal neck, a reverse conical neck, narrow access vessels, and inclusion of important branch vessels by the aneurysm are all factors that preclude its more widespread use.

To circumvent this problem and enhance the applicability of EVAR to more complex aneurysms, fenestrated and branched stent grafts, which allow for the continued perfusion of renal and visceral vessels, were developed. The earliest of these devices was successfully deployed in 1999.[3] Studies have demonstrated use of fenestrated stent grafts have comparable perioperative mortality rates to conven-

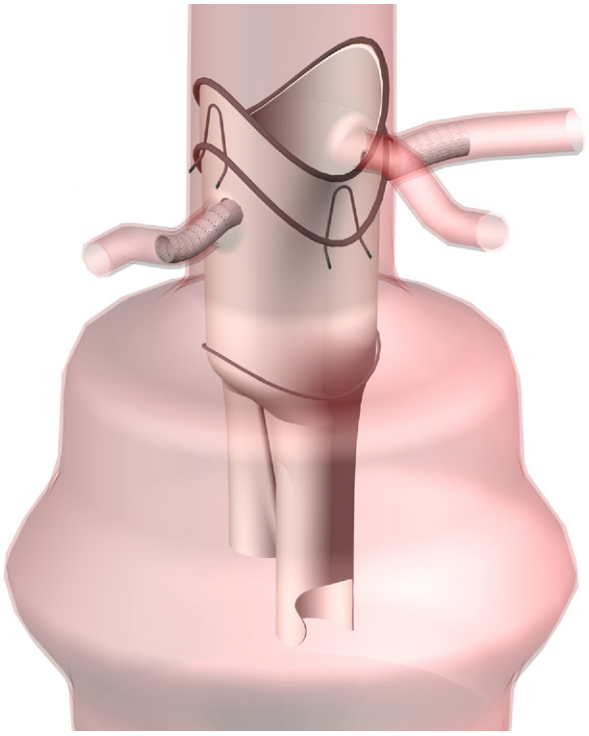

Fig 1. An illustration of a custom fenestrated Anaconda shows two fenestrations for the renal arteries and superior mesenteric artery accommodated in the anterior valley.

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Competition of interest: L.M. is employed by Vascutek Ltd, as a clinical support specialist. She worked on the research and development and planning of the cases. N.J.B. has a contract with Vascutek as a consultant; however, has received no fees relating to this manuscript or any other project with Vascutek. P.M.B. has a consultancy contract with Vascutek UK.

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Table I. Outline of patient demographics, comorbidity, and outcome after fenestrated stent graft placement[a]

Pt	*Age (years)*	*Sex*	*Comorbidity*	*ASA score*	*AAA AP diameter (mm)*	*Indications for FEVAR*
1	76	M	NIDDM Hypertension Paroxysmal AF Hyperthyroidism AVR Left RA stenosis	3	74	Juxtarenal
2	78	F	NIDDM CKD Hypertension	2	91	Short neck
3	79	M	Ischemic heart disease Hypertension Smoker PVD Renal cell carcinoma	3	64	Juxtarenal
4	73	M	Hypertension Abdominoperineal resection for colorectal cancer Former smoker	2	56	Short neck

AF, Atrial fibrillation; *AP,* anteroposterior, *ASA,* American Society of Anesthesiologists; *AVR,* aortic valve replacement; *CKD,* chronic kidney disease; *EBL,* estimated blood loss; *F,* female; *FEVAR,* fenestrated endovascular aneurysm repair; *LOS,* length of stay; *M,* male; *NIDDM,* non–insulin-dependent diabetes mellitus; *NSTEMI,* non-ST elevation myocardial infarction; *PVD,* peripheral vascular disease; *RA,* renal artery; *SMA,* superior mesenteric artery.
[a]All patients had two renal fenestrations.

tional stents used in EVAR, as well as high immediate and midterm target vessel patency rates with a low rate of secondary interventions.[4-6] Despite this, although a Conformité Européene mark has been obtained in Europe, fenestrated stent grafts are still at the clinical trial phase in the United States.

The aim of this study was to report on the feasibility of the Anaconda fenestrated stent graft (Vascutek, Inchinnan, United Kingdom), with its benefits of a repositionable main body, for repairing AAAs that are anatomically unsuitable for conventional EVAR.

METHODS

Patient selection. Between June and November 2010, four patients with asymptomatic high infrarenal AAA underwent elective deployment of the Anaconda fenestrated stent graft at two institutions in the United Kingdom. Indications for fenestrated EVAR device placement included an AAA with a maximum diameter of ≥5.5 cm and unfavorable neck anatomy for conventional EVAR. Unfavorable anatomy was defined as an aortic neck length <10 mm, a conical neck, or an aneurysm that involved the visceral vessels.

All patients underwent preoperative assessment of their AAA using multislice high-resolution spiral computed tomography angiography (CTA). Images were taken from the distal descending thoracic aorta to the proximal superficial femoral artery. Multiplanar and three-dimensional workstation reconstructions were used to evaluate the anatomy of the aneurysm. The decision to perform fenestrated

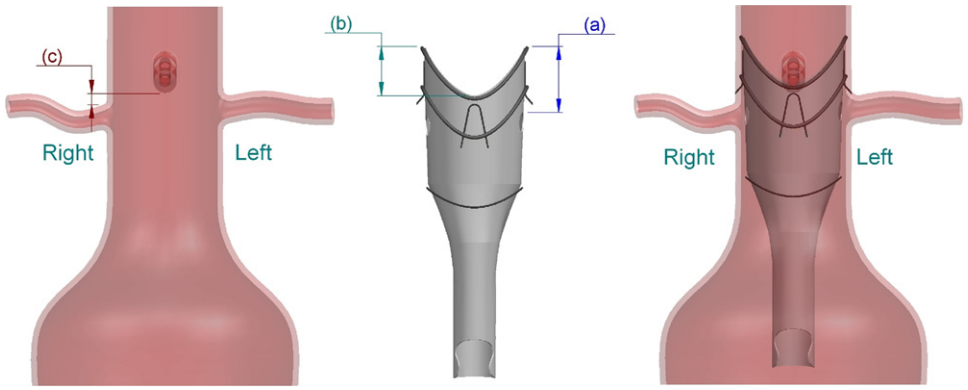

Fig 2. When planning for Anaconda custom fenestrated devices, the distance from the superior mesenteric artery (SMA) to the renal arteries is measured (*c*). The stent graft design takes into consideration the oversize of the device and the relative distance from the peak to the valley (*b*), to allow flow to the SMA. The distance from the peak of the device to the top of the fenestration (*a*) is also calculated for accurate placement below the sealing zone in the suprarenal aorta.

Table I. Continued.

Infrarenal neck length (mm)	*Method of SMA accommodation*	*EBL (mL)*	*Contrast volume (mL)*	*Screening time (minutes)*	*Peri-op complications*	*LOS (days)*
0	Valley	500	200	80	Type Ib endoleak	8
3	Valley	300	200	78	Bilateral groin hematomas	8
0	Valley	580	65	53	Complete heart block NSTEMI Heart failure Groin hematoma	16
5	Augmented valley	360	250	59	None	3

EVAR was made after multidisciplinary team discussion of each patient. Devices were customized to include fenestrations for visceral vessels that were regarded as essential and could not be excluded (Fig 1). Informed consent was obtained preoperatively for all patients.

Technical aspects of the Anaconda AAA stent graft system. The device is customized for individual patient use and based on the design of the Conformité Européene approved Anaconda AAA stent graft system (Fig 2). The peaks of the ring stent device are placed suprarenally in a lateral position (in contrast to conventional deployment in which the peaks are positioned anteriorly and posteriorly), allowing flow to the superior mesenteric artery (SMA), which sits in the anteriorly oriented valley. The depth of the valley can be adjusted with the amount of oversize between the native vessel and the ring stent diameter or, in the case of one patient in this series, with an augmented anterior valley/scallop because the distance between the SMA and renal arteries was <5 mm.

The fenestrations are placed in the unsupported region of the graft body and therefore their positioning is not compromised by any stents or wires. Each fenestration is supported with a nitinol ring stent. The Anaconda custom fenestrated body can be repositioned. Hence, even after complete unsheathing of the device, the physician is still able to partially collapse and change the orientation or height of the stent graft and therefore correct for any mismatch between the fenestrations and the target vessel ostia.

Stent graft planning. Planning for the fenestrated Anaconda was performed from CTA, as with standard infrarenal EVAR. The orientation and level of the celiac, SMA, and renal arteries were all considered. Before implantation, prototype grafts made for all four patients were deployed into plastic models of the aorta created from the CT data to verify correct positioning of the fenestrations and clearance of the SMA ostia.

Stent graft placement. All procedures occurred in the interventional radiology suite with the patients under general anesthesia. An arterial catheter and urinary catheter were placed perioperatively for monitoring purposes. Patients were admitted to a high-dependency unit after the procedure.

All patients received 5000 U of heparin intravenously immediately before femoral artery cannulation, with additional boluses of heparin given as required, or as a continuous infusion adjusted according to the intraoperative activated clotting time (ACT) values. The Anaconda stent graft system used in this study is a modular device composed of a fenestrated main body and two iliac extension limbs. Bilateral open femoral artery exposure allowed for access for the stent graft deployment system. The main body of the graft was initially deployed, followed by cannulation of the fenestrations with subsequent Atrium V12 (Atrium, Hudson, NH) covered stent placement within the renal arteries. To aid orientation and facilitate accurate alignment, as well as identify fenestrations, the Anaconda fenestrated stent graft device has radiopaque markers. Imaging was performed using a C-arm, and a completion angiography was performed in all patients after stent graft placement to ensure adequate exclusion of the aneurysm.

Follow-up. After stent graft placement, patients were studied prospectively. Postoperatively, endograft placement was assessed clinically and using Doppler ultrasound imaging. When potential complications were a concern, a CTA was undertaken. Laboratory assessment of renal function was performed routinely in all

Table II. Technical aspects of Anaconda stent graft placement

Pt	*Ring stent size (mm)*	*Size proximal native aorta (mm)*	*Percentage oversize (%)*	*Size of left renal fenestration (mm)*	*Size of atrium V12 covered stent used on left (mm)*	*Size of right renal fenestration (mm)*	*Size of atrium V12 covered stent used on right (mm)*	*Length of sealing zone (mm)*
1	32	26	23	8	7[a]	6	6	15
2	32	28	14	6	6	6	6	8
3	32	27	19	6	6	6	6	7
4	34	28	21	8	7[a]	8	7[a]	5

[a]Postdilated to 8 mm.

patients periprocedurally. All patients on discharge from hospital were entered into a surveillance program with follow-up at 1 month, 6 months, and 1 year with blood tests for assessment of renal function and CTA of the aortic stent graft.

RESULTS

Demographic data. Four patients (three men, one woman) underwent Anaconda fenestrated stent graft placement. Patients were of American Society of Anesthesiology (ASA) grade 2 or 3, and their comorbidities and demographic data are summarized in Table I. The patients were a mean age of 76.5 years (range, 73-79 years). The mean neck length was 2 mm (range, 0-5 mm). The mean diameter of the supra-renal sealing zone was 28.5 mm (range, 26-31 mm; Table II). One patient had a moderate neck angulation of 50°, but no patient had a severe (>60°) angulation of the proximal neck or thrombus involving more than two-thirds of the proximal landing zone diameter. Indications for fenestrated EVAR included a short neck in two patients, a juxtarenal aneurysm in two, and a conical neck in one. Mean maximum aneurysm diameter was 71 mm (range, 56-91 mm). The proximal graft diameter, sizing of fenestrations and Atrium V12 covered stents, and length of the sealing zones are detailed in Table II. All of the Atrium stents were postdilated/flared at the fenestration to create a seal between the Atrium and Anaconda stent grafts. The proximal neck did not undergo any molding in any of the patients described.

Mean procedure time was 261 minutes (range, 181-315 minutes), mean fluoroscopy time was 67.5 minutes (range, 53-80 minutes), and 179 mL of iodinated contrast (range, 65-250 mL) was used per case (Table I).

Eight fenestrations with covered stents for renal arteries and four SMA valleys/scallops were used. Selective catheters were used to localize and catheterize branch vessels, and the target vessel cannulation success rate was 100%. All target branch vessels remained perfused after the procedure. In one patient, an accessory renal artery was intentionally covered. Completion angiography demonstrated successful exclusion of the aneurysm in all patients (Figs 3-6).

Perioperative results. There were no perioperative deaths. The mean estimated intraoperative blood loss was 435 mL (range, 300-580 mL). Perioperative morbidity included groin hematomas in two patients and complete heart block and myocardial infarction complicated by heart failure in one patient. The mean inpatient hospital length of stay was 8.75 days (range, 3-16 days; Table I). There was no difference in preoperative or postoperative serum creatinine levels ($P = .42$), and no patient required dialysis.

Follow-up. All patients have undergone 1-month follow-up, and no patient has been lost to follow-up. No aneurysm-related or aneurysm-unrelated deaths have been reported. One patient had CTA evidence of a type Ib endoleak and underwent balloon angioplasty of the right iliac sealing zone, with successful resolution of the endoleak. Renal function remained unchanged at follow-up ($P = .30$), and no target vessels were occluded. Patient 1 has also had 6-month follow-up and is well, with all stents patent, no endoleak, and preserved renal function.

DISCUSSION

Fenestrated endovascular stent grafts offer patients who are likely to be at high risk for surgery because of a hostile aneurysm anatomy,[4] a therapeutic option that has lower perioperative mortality rates compared with open repair.[6] Each stent graft is tailored to the individual patient, and therefore, careful planning and collaboration with the manufacturer is required. This currently precludes their use for the treatment of ruptured or symptomatic AAAs. Furthermore, fenestrated stent graft deployment requires expertise and should be performed by a team familiar with the stent graft device and its deployment system.

Although this is a very small series, and long-term follow-up data are not yet available, immediate and short-term results suggest the Anaconda fenestrated stent graft is a potentially efficacious method for treating complex AAAs that are not suitable for conventional EVAR. Although greater contrast volumes are required than for conventional EVAR,[7] no renal complications developed in the patients in this series. In addition, all target vessels were successfully cannulated, and none were lost during the intervention. One reason for acute branch vessel loss is anatomic factors, and these can affect the versatility of the device and its delivery system. Significant proximal

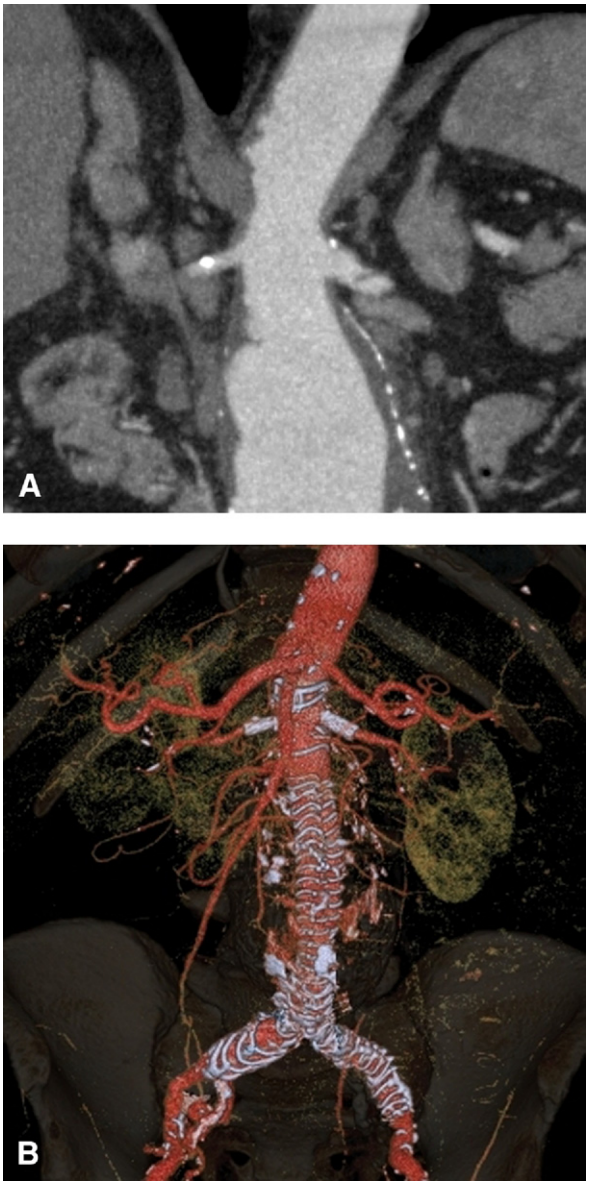

Fig 3. A, A computed tomography angiography (CTA) reconstruction of the 74-mm juxtarenal abdominal aortic aneurysm is shown for patient 1. A web-like stenosis of the left renal artery is clearly seen. **B,** A volume-rendered reconstruction of the 6-month follow-up CTA shows the fenestrated graft has excluded the aneurysm.

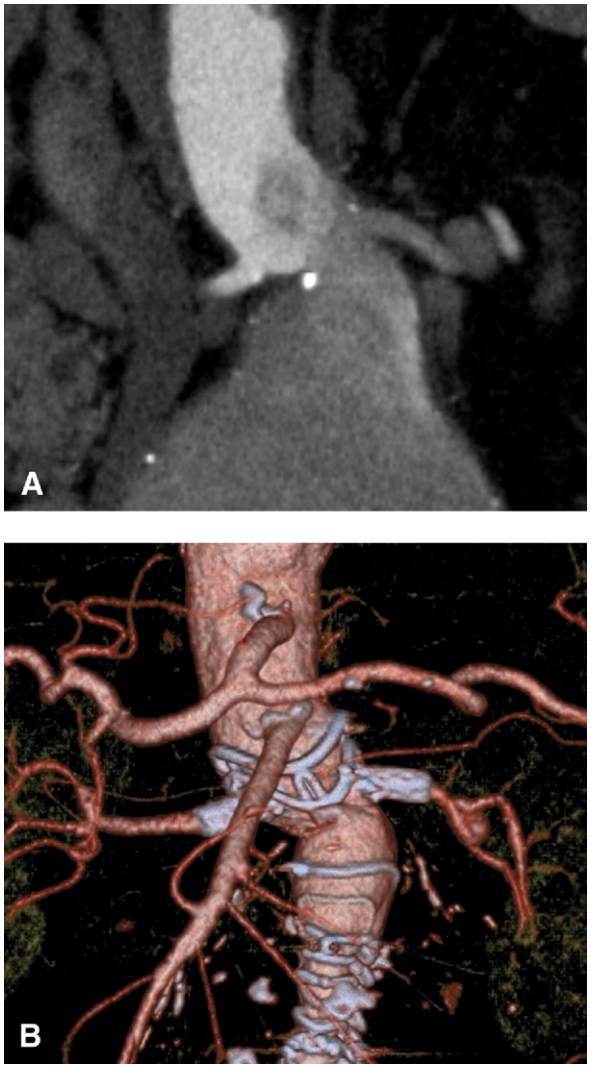

Fig 4. A, A computed tomography angiography (CTA) reconstruction shows the short neck of the aneurysm in patient 2, and a 50° angulation is seen in this coronal plane. **B,** A volume-rendered reconstruction of the 1-month follow-up CTA shows the graft conforms to the angulated neck anatomy, patent renal stents/arteries, and the superior mesenteric artery is accommodated within the anteriorly oriented valley of the proximal graft.

aneurysm neck angulation, small aneurysm neck diameter, calcification, and tortuous iliac vessels are all factors associated with acute target vessel loss and may lead to maldeployment.[4]

One advantage of the Anaconda custom fenestrated stent body is that it can be repositioned: after the device is unsheathed, it can be partially collapsed and the orientation or longitudinal position of the stent graft altered. This facilitates accurate initial deployment with respect to the visceral arteries and also allows for easy correction of any mismatch between fenestrations and target vessels that may arise during the procedure. Below the proximal sealing stents, the main body of the graft consists of unsupported fabric; consequently, there is no limitation on fenestration size or position. This feature also simplifies stent graft planning and manufacture, and may make the fenestrations and renal stents less prone to compromise on long-term follow-up, even in the presence of aneurysm remodeling or stent graft migration.

At the 1-month follow-up, all target vessels remained patent in this series. We recognize, however, that most

Fig 5. A, A computed tomography angiography (CTA) maximum intensity projection (MIP) image for patient 3 shows the neck anatomy before fenestrated endovascular aneurysm repair (FEVAR). **B,** A CTA MIP image shows the position of the stent graft and renal artery stents after FEVAR.

Fig 6. A, A computed tomography angiography (CTA) maximum intensity projection (MIP) in patient 4 shows the neck anatomy before fenestrated endovascular aneurysm repair (FEVAR). **B,** The CTA MIP image shows the position of the stent graft and renal artery stents after FEVAR.

stent occlusions occur in the first year[8] and that longer-term follow-up data are therefore required to fully evaluate target vessel patency with this device. Perioperative morbidity in our series was also acceptable[6]; a type Ib endoleak developed in one patient, which was easily remedied. With a small series it is difficult to interpret this event, in the context of the literature, which reports type I and III endoleak rates of between 1.7% and 13%.[5,8]

CONCLUSIONS

Four patients with AAAs underwent fenestrated endovascular stent graft placement using the newly developed Vascutek Anaconda fenestrated stent graft system. A total of 12 visceral vessels were accommodated with 8 fenestrations for renal arteries and 4 SMA valleys/scallops. One type Ib endoleak was identified at follow-up, and this was successfully treated with balloon dilatation.

From this preliminary study, we conclude that the Anaconda fenestrated stent graft device is feasible for the repair of AAAs with hostile neck anatomy that renders them unsuitable for conventional EVAR. The unique advantage the Anaconda stent graft has over conventional EVAR is the ability to be repositioned, which allows for accurate initial deployment of the device and facilitates adjustment of the stent graft main body and fenestrations to allow for correction, if required, of target vessel to fenestration misalignment during the procedure.

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